

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b> <hr/> <b>THIS DOCUMENT RELATES TO:</b>  <b>WAVE 3 CASES LISTED IN PLAINTIFFS' EXHIBIT A</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE  
CERTAIN OPINIONS AND TESTIMONY OF JOSEPH CARBONE, M.D.**

In the Court's order on Plaintiff's motion to exclude in Wave 1, the Court excluded Dr. Carbone's undisclosed testimony on his personal complication rate. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2327, 2016 WL 4958312, \*3 (S.D. W. Va. Aug. 25, 2016). Defendants offer nothing in this Wave 3 to demonstrate that the omission was substantially justified or harmless, so the testimony should be excluded here as well.

As for product warning testimony, the Court previously ruled that Dr. Carbone is not qualified to testify on what risks the IFUs should or should not have disclosed. *Id.* That ruling should apply to all risks – whether Dr. Carbone contends that the risks are associated with mesh specifically, associated with pelvic surgery generally, or commonly known.

**ARGUMENT**

**I. Dr. Carbone's failure to disclose his personal complication rate opinions is not substantially justified or harmless.**

Defendants have not established that Dr. Carbone's nondisclosure of his personal complication rate opinions is substantially justified or harmless. *See, e.g., Salgado v. Gen'l Motors Corp.*, 150 F.3d 735, 741 n.6 (7<sup>th</sup> Cir. 1998) (Exclusion of testimony is automatic and

mandatory unless the sanctioned party can show its violation of Rule 26(a) was either justified or harmless). The analysis involves a five-factor test: “(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to name the witness before trial; and (5) the importance of the testimony.” *Eghnaham v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 718 (S.D. W.Va. 2014).

As for the first factor, Defendants contend that there was no surprise to Plaintiffs because Dr. Carbone’s personal-rate testimony is “merely an elaboration” of his disclosed opinions, namely regarding complication rates in medical literature. Dkt. No. 2915 at 2. This is essentially the same argument Defendants raised in Wave 1. *See* Dkt. No. 2180 at 5 (arguing that there is no Rule 26 violation because the report is “replete with statements about complications and complication rates”). In its August 25, 2016 Order, the Court rejected that argument: “The concern is not whether the report includes complication rates found in medical literature – which it does; instead the concern is whether the report includes Dr. Carbone’s complication rates and a comparison of those rates to the rates found in the medical literature – which it does not.” *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4958312, at \*3. The Court concluded that Defendants had not offered “any argument that this failure to disclose was substantially justified or harmless,” and excluded the testimony. *Id.*

The reality is that, as Defendants themselves admit, Dr. Carbone did not disclose his personal complication rate in his reports. *See* Dkt. No. 2915 at 2. Further, Defendants do not even address the failure to produce a single document in support of Dr. Carbone’s purported complication rate testimony. Under these undisputed facts, Plaintiffs were necessarily surprised by the undisclosed testimony.

As for the second factor, Defendants cannot use Dr. Carbone's deposition as a "cure" for the failure to disclose the opinions. In the first day of Dr. Carbone's deposition, Plaintiffs' counsel asked Dr. Carbone if he had ever endeavored to do a survey or study of his exact complication or failure rate, and he said no. Carbone TVT Dep., 3/16/16, excerpts attached as Ex. A, at 70:13-71:6. That testimony is consistent with the undisputed fact that Dr. Carbone did not disclose a personal complication rate in his reports. However, on the second day of the deposition, and on prompting from Defendants' counsel, Dr. Carbone suddenly disclosed that he had his office manager "look up" codes to determine his complication rate, and derive an opinion relative to rates in the literature:

Q (by Mr. Rosenblatt): Doctor, in your practice have you gone back and done any type of systematic review of your complications?

A: I've asked my office manager to look up the ICD-9 codes for erosion of the mesh for the vagina, and she was able to provide for me several years of ICD-9 – well, ICD-9 and ICD-10 codes now, and that's how I was able to come up with the number of complications that I quoted.

Q: And based on these complication codes or CPT or – what was the –

A. ICD-9 and ICD-10 coding.

Q: Based on that coding, what were you able to determine, based on the data available, was your complication rate for mesh erosions?

A: I would say my complication rate was a little lower than the reported complication rate in the medical literature, the randomize control trial, the analysis.

Carbone TVT Dep., 3/17/16, excerpts attached as Ex. B, at 109:22-110:22. Plaintiffs had no notice of any such review or opinion, or for that matter, any specific personal percentage rate. And no document was produced regarding his coding records, a purported review of those records, or his complication rate, so that Plaintiffs could not meaningfully question Dr. Carbone on this issue.

An expert report is supposed to include the “‘how’ and ‘why’ the expert reached a particular result, not merely the expert’s conclusory opinions.” *Washington v. McKee*, No. 4:06-cv-6, 2006 WL 2252064, \*2 (E.D. Va. Aug. 3, 2006) (citing *Salgado*, 150 F.3d at 741 n.6). As the Seventh Circuit has cogently stated, “[t]he report must be complete such that opposing counsel is not forced to depose an expert in order to avoid ambush at trial[.]” *Salgado*, 150 F.3d at 741 n.6. Defendants’ attempt to use Dr. Carbone’s deposition as a cure-all runs afoul of these principles.

While the third factor is not implicated, the fourth and fifth factors also weigh in favor of excluding the opinion testimony. Defendants provide no real explanation for the omission. Logic does not dictate that an omission is unintentional merely because it is consistent with other evidence. *See* Dkt. No. 2915 at 3. Moreover, the personal complication testimony is not consistent with the cited literature. According to Dr. Carbone, his rate is *lower* than published rates, so that he is not simply corroborating the literature, and the omission is not harmless.

For each and all of these reasons, the omission is not substantially justified or harmless, and should be excluded. Additionally, this Court has previously excluded “ballpark figure” estimates of complication rates in a physician’s practice. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prdt. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, \*3 (S.D. W.Va. Sept. 1, 2016). Similarly here, Dr. Carbone’s purported complication rate testimony is unreliable, and should be excluded, for the reasons previously set forth in Plaintiffs’ opening brief (Dkt. No. 2027) and incorporated by reference in this Wave 3 (Dkt. No. 2761).

**II. Dr. Carbone should not be allowed to testify about the adequacy of Defendants' product warnings and IFU, regardless of whether the risks are specific to mesh or not.**

In its August 25, 2016 Order, the Court held that Dr. Carbone may testify about the specific risks of implanting mesh and whether those risks appeared in the relevant IFU. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4958312, at \*3. The Court further held that Dr. Carbone is not qualified to offer expert testimony about what an IFU should or should not include, and excluded his testimony on that issue. *Id.* The Court has elsewhere indicated that the same ruling applies even if the risks are not associated with mesh specifically:

In relation to the expert testimony about the adequacy of the IFU, Ethicon claims Dr. Toglia is qualified to testify about whether certain risks were commonly known in the medical community. In my view, this is not the subject of the plaintiffs' motion. The plaintiffs' motion focuses on whether Dr. Toglia is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Toglia may testify about whether certain risks were common knowledge. *However, an expert cannot testify about whether **any risks** should have been included in an IFU unless he or she possess additional expertise – expertise Dr. Toglia does not possess.*

*In re: Ethicon, Inc. Pelvic Repair Sys. Prdt. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, \*4 n.2 (S.D. W.Va. Aug. 25, 2016) (emphasis added).

That rule is particularly apt here, given that Dr. Carbone's unqualified warning opinions are specifically tied to risks that he contends are commonly known. For example, in his TVT Report he states:

The TVT IFU adequately warns of all risks and potential complications associated with the TVT. These risks are well known to the medical community. Even the FDA has acknowledged that the risks known to be common to pelvic floor surgery (even without mesh) include pain, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring.

The TVT IFU fairly and completely informs reasonably prudent surgeons about the TVT, including the procedure and the associated risks and potential complications.

Ex. B to Pls. Mot. (Dkt. 2025-2) at 20 (footnote omitted). Defendants should not be allowed an end-run around the Court's prohibition on testimony regarding the adequacy of product warnings, or regarding FDA-related testimony, through Dr. Carbone's opinions on risks that he opines are associated with any pelvic surgery or commonly known.

### **CONCLUSION**

Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Joseph Carbone, M.D., for Wave 3 cases should be granted for the reasons set forth above, and in Plaintiff's Memorandum in Support submitted in Wave 1 (Dkt. No. 2027) and adopted in Wave 3 (Dkt. No. 2761).

Dated this 21st day of October, 2016.

Respectfully submitted,

By: /s/ Thomas P. Cartmell

Thomas P. Cartmell MO # 45366

Jeffrey M. Kuntz MO # 52371

Wagstaff & Cartmell LLP

4740 Grand Avenue, Suite 300

Kansas City, MO 64112

Telephone: (816) 701-1100

Facsimile: (816) 531-2372

[tcartmell@wcllp.com](mailto:tcartmell@wcllp.com)

[jkuntz@wcllp.com](mailto:jkuntz@wcllp.com)

*Counsel for Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that on October 21, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Thomas P. Cartmell

Thomas P. Cartmell